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May 4, 2021

VIA CM/ECF AND HAND DELIVERY

The Honorable Sherry R. Fallon
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801

Re: *Avion Pharmaceuticals, LLC and RxOmeg Therapeutics, LLC, a/k/a Romeg Therapeutics, LLC v. Granules Pharmaceuticals, Inc., C.A. No. 20-898 (LPS)*

Dear Judge Fallon:

Plaintiff RxOmeg Therapeutics, LLC, a/k/a Romeg Therapeutics, LLC (“Romeg”) respectfully submits this responsive letter regarding the parties’ protective order dispute. The dispute centers on Defendant Granules Pharmaceuticals, Inc.’s (“Granules”) request for the Court to impose contested patent prosecution and regulatory/FDA bars in the protective order. Romeg opposes the imposition of these bars based on the prejudice they would cause to Romeg, and asks the Court to adopt the attached version of the parties’ proposed protective order that does not include such bars. *See* Ex. 1.¹

To be clear, the parties agree that the opposing party’s confidential information may not be used for any other purpose than this litigation. *See* Ex. 1 at ¶ 5. Granules, however, seeks additional restrictions that would prevent any Romeg in-house personnel with access to confidential information from participating in any patent prosecution activities, or the preparation or filing of Citizens Petitions or Suitability Petitions with Food and Drug Administration (FDA), relating to colchicine oral solution drug products.² Any risk posed by the possibility of inadvertent disclosure of Granules’s confidential information, however, is substantially outweighed by the harm to Romeg should a patent prosecution bar be imposed. Moreover, Granules has failed to

¹ Aside from different language in ¶ 5 and the absence the prosecution and regulatory bars (¶ 17 of Granules’s proposed protective order, D.I. 36-1, Ex. A), the remaining language of Romeg’s proposed protective order is the same as Granules’s proposed protective order.

² During the parties’ discussions, Granules clarified the meaning of “related litigation” and “colchicine oral solution and drug products” as drafted in Granules’s proposed ¶ 17. Romeg noted that Granules’s proposed language did not (and still does not) reflect the meaning described by Granules. *See* D.I. 36-1, Ex. B (emails dated April 8, 2021).

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meet its burden to demonstrate the necessity of a regulatory/FDA bar. Granules's request to impose these bars on Romeg should thus be rejected.

Relevant Factual Background. Founded in May 2015, Romeg is an exceptionally small company with only one product, Gloperba[®], which is the subject of this litigation. Only three individuals constitute Romeg's team: Indu Muni, Ph.D.; Gita Muni, M.S., M.T.; and Naomi Vishnupad, Ph.D. *See* Ex. 2 (Vishnupad Decl.) at ¶¶ 2, 5. No other individuals are employed by Romeg.³ Dr. Muni, Romeg's CEO, and Dr. Vishnupad, Romeg's Chief Scientific Officer, share responsibility for the day-to-day activities of Romeg.⁴ *See id.* at ¶¶ 7, 9-10. Dr. Muni and Dr. Vishnupad are responsible for all litigation matters involving Romeg. *Id.* at ¶ 7. They also have sole responsibility for Romeg's patent prosecution activities and regulatory activities. *Id.* at ¶¶ 9-10. There are no other individuals, aside from Dr. Muni and Dr. Vishnupad, at Romeg that can handle Romeg's litigation matters, patent prosecution activities, or regulatory activities. *See id.* at ¶¶ 7, 9-10. Imposition of patent prosecution and regulatory/FDA bars would thus entirely bar Romeg's in-house personnel from participating in this litigation and prosecuting its case.

Argument. To obtain any protective-order provision, the requesting party must demonstrate "good cause" pursuant to Fed. R. Civ. P. 26(c). To justify imposition of a patent prosecution bar, the movant "must show that the information designated to trigger the bar, the scope of activities prohibited by the bar, the duration of the bar, and the subject matter covered by the bar reasonably reflect the risk presented by the disclosure of proprietary competitive information." *In re Deutsche Bank Trust Co. Ams.*, 605 F.3d 1373, 1381 (Fed. Cir. 2010). Should a court determine that such a risk exists, the court "must then 'balance' that risk against the potential harm to the moving party" should the bar be adopted. *PhishMe, Inc. v. Wombat Security Techs.*, No. 16-403 (LPS) (CJB), 2017 WL 4138961, at *2 (D. Del. Sept. 8, 2017). Here, any risk of inadvertent disclosure of Granules's information does not outweigh the significant harm that Romeg will face if a patent prosecution bar is imposed.

As an initial matter, given the parties' agreement that confidential information disclosed in this litigation may only be used for this litigation, a patent prosecution bar is unnecessary and would be duplicative of paragraph 5 of the parties' proposed protective order. *See* Ex. 1 at ¶ 5. Paragraph 5, which forbids use of confidential information for any other purpose other than this litigation, including for "business, research, development, commercial, competitive, [or] regulatory" means, extends to patent prosecution and provides the necessary protections from

³ Granules references Romeg's website, which "lists its leadership as five industry veterans." D.I. 36 at 1. Although listed on the website, Peter Minoie and James Nagle, consultants previously employed by Romeg, left Romeg in July 2019. *See* Ex. 2 (Vishnupad Decl.) at ¶ 6.

⁴ Ms. Muni performs only basic part-time bookkeeping for Romeg and is not involved in Romeg's day-to-day activities. *See* Ex. 2 (Vishnupad Decl.) at ¶ 5. Romeg's finances are handled by an outside accounting firm. *Id.* at ¶ 6.

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inadvertent disclosure and competitive misuse of Granules's information. *See MPG Ingredients, Inc. v. Mars, Inc.*, 245 F.R.D. 497, 502 (D. Kan. 2007) ("The protective order requires almost all persons who are granted access to confidential information to sign an agreement stating that they have read the protective order and that they agree not to use, permit the use of, or disclose to anyone else the confidential information for any purposes other than this lawsuit. Thus, the risk of anyone abusing his or her knowledge of confidential information appears to be small.").

Notwithstanding the fact that a separate prosecution bar is unnecessary here, the significant harm to Romeg should a patent prosecution bar be imposed far outweighs the risk of any inadvertent disclosure of Granules's information. *See Deutsche Bank*, 605 F.3d at 1380 ("Even if a district court is satisfied that such a risk exists, the district court must balance this risk against the potential harm to the opposing party. . . ."). Romeg does not dispute that its in-house personnel, Dr. Muni and Dr. Vishnupad, are competitive decision-makers. *See Ex. 2 (Vishnupad Decl.)* at ¶¶ 8-10; *see also PhishMe*, 2017 WL 4138961, at *3 (finding that individual's oversight of patent prosecution qualified him as a competitive decision-maker). But imposition of a patent prosecution bar will require Romeg to choose between running the day-to-day activities of its business and prosecuting this litigation. *See MPG Ingredients*, 245 F.R.D. at 502 ("Prohibiting MGPI employees from having access to discovery materials in this case could impair its ability to prosecute its claims against defendants[.]"). Having Dr. Muni or Dr. Vishnupad delegate their involvement in Romeg's patent prosecution activities to someone else, as Granules suggests, is not possible, given the size of Romeg: there is no one to whom they could delegate, nor is there anyone who could take their place in overseeing the litigation. *See Ex. 2 (Vishnupad Decl.)* at ¶¶ 7-8.

Further, should a patent prosecution bar be imposed, outside counsel will be restricted from consulting with Romeg on anything regarding its case. Although some courts in this District have found representation by outside counsel to alleviate the harm a patent prosecution bar imposes, *see PhishMe*, 2017 WL 4138961, at *9, as inventors of the asserted patents, Dr. Muni and Dr. Vishnupad have specialized knowledge regarding the technology covered by the asserted patents, something that cannot be compensated for by outside counsel or experts. *See MPG Ingredients*, 245 F.R.D. at 502 (permitting in-house personnel access to confidential material because they had "substantial experience in a narrow field that cannot be replaced in the 'open market'"). Not only will imposition of a patent prosecution bar cause Romeg to be kept in the dark regarding this litigation, but Romeg will be unable to provide any insight to its counsel at all. Therefore, the significant harm to Romeg outweighs any risk to Granules's information, particularly given the parties' agreement that confidential information may only be used for this litigation.

The question of whether the Court should grant Granules's request for a regulatory/FDA bar is governed by Third Circuit law, because a regulatory bar is not patent-specific. The movant must therefore demonstrate that it will suffer "clearly defined, specific and serious injury" absent a regulatory/FDA bar, a showing for which "broad allegations of harm are not sufficient." *Shingara v. Skiles*, 420 F.3d 301, 306 (3d Cir. 2005) (citing *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786-87 (3d Cir. 1994)); *see also Mayne Pharm. Int'l v. Merck & Co., Inc.*, No. 15-438

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(LPS), D.I. 47 at 14:6-8 (D. Del. Mar. 17, 2016) (attached as Ex. 3) (applying the *Pansy* factors in considering whether to adopt an FDA bar). Although Granules cites Citizen Petitions as the reason a regulatory/FDA bar is needed, FDA can delay an ANDA application in response to a Citizen Petition only if FDA determines that the delay is “necessary to protect the public health.” 21 U.S.C. § 355(q). Moreover, Congress has authorized FDA to “dismiss citizen petitions summarily in order to prevent pharmaceutical companies from using this process to unlawfully extend their monopolies.” *Roxane Labs., Inv. v. SmithKline Beecham Corp.*, 2010 WL 331704, at *1 n.2 (E.D. Pa. Jan. 26, 2010) (citing 21 U.S.C. § 355(q)).⁵ Thus, the potential harm from a Citizen Petition is overstated and certainly not enough to amount to the “clearly defined, specific and serious injury” required for a regulatory/FDA bar.

In fact, courts in this District have regularly rejected disputed regulatory/FDA bars in light of the proponents’ failure to identify a clearly defined, serious injury that would result in the absence of a regulatory/FDA bar and where, as here, the proposed protective order already precluded the use of confidential information in such contexts. *See, e.g., Mayne Pharm.*, C.A. No. 15-438 (LPS), D.I. 47 at 13:17-15:16 (attached as Ex. 3) (“[A]ll of the examples that the plaintiff points to for what it is concerned with are in reality intentional acts that are already prohibited under the agreed-upon portions of the portions of the protective order. So I don’t see anything to be accomplished by the inclusion of the FDA bar.”); *Alza Corp. v. Par Pharm. Inc.*, C.A. No. 13-1104 (RGA), D.I. 78 at 26:7-15 (D. Del. Dec. 17, 2013) (attached as Ex. 4) (“[T]he risk of an inadvertent disclosure is so minimal . . . [T]he burden you have to show that there should be a bar that extends to the FDA proceedings, I don’t think you’ve met that, so I’m going to deny.”); *Cephalon, Inc. v. Impax Labs.*, No. 11-1152 (SLR), D.I. 56 at 2 (D. Del. June 29, 2012) (attached as Ex. 5) (rejecting the imposition of a FDA bar as “use of confidential, litigation-generated information for a citizen petition is very much an intentional disclosure already governed by the protective order in place”). Granules cites no case, and Romeg is aware of no case where an FDA bar was imposed over a party’s objection in this District.

Given the significant harm to Romeg should a patent prosecution bar be imposed and Granules’s failure to meet its burden to show that a regulatory/FDA bar is necessary here, Granules’s request should be denied.

Respectfully,

/s/ Ian R. Liston
Ian R. Liston (#5507)

cc: Clerk of Court (via Hand Delivery)
All Counsel of Record (via E-mail and CM/ECF)

⁵ Granules cites no case law, and Romeg is aware of no case, to indicate that the standard concerning Suitability Petitions is different.